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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,514	12/18/2001	Philip J. Barr	368292000200	6421

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EXAMINER	
WALICKA, MALGORZATA A	
ART UNIT	**PAPER NUMBER**
1652	9

DATE MAILED: 07/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,514	BARR ET AL.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2, 4, 8 in part, 11, 16, 17, drawn to a fusion protein comprising a first protease inhibitor comprising alpha 1- antitrypsin, or a functionally active portion thereof, and a second protease inhibitor that is a secretory leukocyte protease inhibitor, or a functionally active portion thereof classified in class 435, subclass 69.2.

II. Claim 3, 8 in part, 12, 15, 18, 19, 20, drawn to a fusion protein comprising a first protease inhibitor comprising alpha 1- antitrypsin or a functionally active portion thereof and a second protease inhibitor that is a tissue inhibitor of metalloprotease, or a functionally active portion thereof (amino acids 1-107), classified in class 435, subclass 69.2.

III. Claim 3, 8 in part, 12, 21, 22, 23, drawn to a fusion protein comprising a first protease inhibitor comprising alpha 1- antitrypsin or a functionally active portion thereof, and a second protease inhibitor that is a tissue inhibitor of metalloprotease, or a

functionally active portion thereof (amino acids 1-184), classified in class 435, subclass 69.2.

IV. Claim 3, 8 in part, 12, 21, 22, 23, drawn to a fusion protein comprising a first protease inhibitor comprising alpha 1- antitrypsin or a functionally active portion thereof, and a functionally active portion of a tissue inhibitor of metalloprotease, (S-linked TAPI), classified in class 435, subclass 69.2.

V. Claims 1 and 13 drawn to a fusion protein comprising a first protease inhibitor comprising alpha 1- antitrypsin, or a functionally active portion thereof, and a second protease inhibitor that inhibits an aspartyl protease, classified in class 435, subclass 69.2.

VI. Claims 1 and 14 drawn to a fusion protein comprising a first protease inhibitor comprising alpha 1- antitrypsin, or a functionally active portion thereof, and a second protease inhibitor that inhibits a cysteine protease, classified in class 435, subclass 69.2.

VII. Claims 5, 6, 7, 9, and 10, drawn to a polynucleotide encoding the fusion protein of claim 1, expression vector, host cell comprising

said vector, recombinant method of production the fusion protein, classified in class 435, subclass 69.7.

VIII. Claim 26-28, drawn to a method for inhibiting protease activity, classified in class 435, subclass 23.

IX. Claim 29-35, drawn to a method of treating an individual comprising administering to the individual an effective amount of the fusion protein classified in class 514, subclass 12.

In addition, inventions VII, VIII and IX above are generic to a plurality of disclosed patentably distinct species comprising:

(A). fusion protein of claim 1.

(B). fusion protein of claim 2.

(C). fusion protein of claim 3.

(D). fusion protein of claim 4.

Therefore, election is required of one of inventions I-IX and one of inventions (A)-D.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (A) through (D), even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions I-IX are distinct, each from the other because of the following reasons:

Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent structurally different fusion polypeptides being inhibitors of different proteases. Therefore, they are not capable of use together.

Inventions VII and I-VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the fusion polypeptides of inventions I-VI can be produced not recombinantly but chemically.

Inventions I-VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups I-VI can be used to produce antibodies and not to inhibit proteases.

Inventions I-VI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups I-VI can be used to produce antibodies and not to be used in a treatment of patients.

Inventions VII and VIII–IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions: DNA encoding the fusion proteins, the method of inhibiting proteases and the method of treating of patents are not disclosed as capable of use together.

Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods, of inhibiting proteases and treating of patents are not disclosed as capable of use together.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

Art Unit 1652

Assistant Patent Examiner

PONNATHAPU ACHUTA MURTHY
SUPERVISORY PATENT EXAMINER